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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,843	03/22/2004	Gonzalo Romero-Matos	ROMERO	3027
7590 04/30/2007 GONZALO ROMERO M APT #2 455 39TH AVE NORTH SAINT PETERSBURG, FL 33703-6118			EXAMINER HOFFMAN, SUSAN COE	
			ART UNIT	PAPER NUMBER
			1655	
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			04/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/805,843	Applicant(s) ROMERO-MATOS, GONZALO	
	Examiner Susan Coe Hoffman	Art Unit 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 10 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/04</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The amendment filed February 5, 2007 has been received and entered.
2. Claims 1-11 are currently pending.

### ***Election/Restrictions***

3. Applicant's election of Group II, claims 9-11 and capsaicin (figure 1a) for the species in the reply filed on February 5, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 1-8 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 5, 2007.
5. Claims 9 and 10 are examined on the merits.

### ***Information Disclosure Statement***

6. The Information Disclosure Statement filed June 22, 2004 has been considered by the examiner. Applicant failed to provided copies of several of the references as required by MPEP section 609. Accordingly, these references could not be considered and the citations have been lined through on the 1449 form.

***Claim Objections***

7. Claim 9 is objected to because of the following informalities: as amended the claim does not end in a period. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They are replete with grammatical and idiomatic errors and contain many narrative phrases that are not consistent with U.S. practice. For examples of proper claim construction, please see the claims in the U.S. patents cited below. In addition to the general grammatical, idiomatic, and narrative problems, specific problems with the claims are set forth below.

9. Claim 9 is indefinite because it is unclear if applicant is intending to claim a composition or a method for using a composition. Patent claims must be directed to one statutory category of invention. It is improper to include two types of categories in one patent claim. Specifically, confusion arises due to the phrase "A fabrication and use."

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP §

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2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation "an active substance," and the claim also recites "such as any a natural and synthetic capsaicin" which is the narrower statement of the range/limitation.

Claim 9 is also indefinite because applicant has cancelled step (b) but has not re-lettered the other steps to reflect this cancellation.

Step (c) in claim 9 is indefinite because the claim lists several "preferred" concentrations for the ethanol. It is unclear what exact range of alcohol applicant intends the claim.

Step (e) in claim 9 is indefinite because the claim lists two diluents and it is unclear if both are required or if only one diluent is required.

Step (f) in claim 9 is indefinite because it is unclear what volumes are encompassed by "high" volume and "low" volume. In addition, it is unclear if the slashes between intramuscular and subcutaneous mean "and" or "or." Finally, the step ends in "and" but there are no further steps in the claim.

10. Claim 10 is indefinite because the antecedent basis for "said diluent" in steps (a) and (c) is unclear. It is unclear if "said diluent" is referring to the first or second diluent from claim 9.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by LaHann (US Pat. No. 4,599,342).

LaHann teaches a composition which comprises capsaicin, 10% ethanol, 10% Tween 80 and saline (see example VIII). The saline used in the reference has a concentration of 0.9% sodium chloride (see column 10, line 61). Thus, the reference teaches a composition that is the same as the composition claimed by applicant. The reference composition comprises all of the same ingredients at the same concentrations claimed by applicant. Therefore, applicant's claimed composition is not considered patentable over the prior art composition.

The reference does not specifically teach that the composition is able to treat HIV and AIDS. However, this is considered a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The reference also does not specifically teach that the composition is made in the same manner claimed by applicant in claim 10. However, this is considered to be a product-by-process claim. Regarding product-by-process claims, note that MPEP § 2113 states that:

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"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate... A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In *re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972) ; In *re Fessmann*, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In *re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaHann (US Pat. No. 4,599,342).

As discussed above, this reference teaches a product that appears to be identical to the product made in applicant's claim 10. However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared ingredients.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

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The reference also does not specifically teach adding the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

13. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungdahl et al. (Journal of the Neurological Sciences (1986), vol, 72, pp. 223-230).

This reference teaches a composition comprising capsaicin, saline, 10% ethanol and 10% Tween 80 (see page 224, "Capsaicin-pretreatment" section).

The reference does not specifically teach using the sodium chloride concentration claimed or using the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person



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of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Thus, this reference teaches a product that appears to be identical to the product made in applicant's claim 10. However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared ingredients.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

The reference does not specifically teach that the composition is able to treat HIV and AIDS. However, this is considered a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

14. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belmonte-Martinez et al. (US Pat. No. 5,525,601).

This reference teaches a composition comprising capsaicin, saline, 8.5% Tween 80 and 1.5% ethanol (see example 6)

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The reference does not specifically teach using the sodium chloride concentration claimed or using the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Thus, this reference teaches a product that appears to be identical to the product made in applicant's claim 10. However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared ingredients.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

The reference does not specifically teach that the composition is able to treat HIV and AIDS. However, this is considered a recitation of intended use. A recitation of the intended use

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of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

15. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blumberg (US Pat. No. 5,290,816).

This reference teaches a composition comprising capsaicin, saline, 10% Tween 80 and 10% ethanol (see example 1)

The reference does not specifically teach using the sodium chloride concentration claimed or using the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Thus, this reference teaches a product that appears to be identical to the product made in applicant's claim 10. However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless,

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have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared ingredients.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

The reference does not specifically teach that the composition is able to treat HIV and AIDS. However, this is considered a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

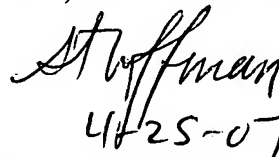
16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Handwritten signature of Susan Coe Hoffman in cursive script, with the number 4425-07 written below it.

Susan Coe Hoffman  
Primary Examiner  
Art Unit 1655